

Appl. No. 10/082,691  
Reply to Office action of January 30, 2004

Remarks

Claims 1-29 were pending, and claims 10, 11, 13-16, 20, 21, 28, and 29 have been withdrawn from consideration. By way of this response, claims 1, 7-9, 17-19, and 22-27 have been amended. Support for the amendments to the specification and the claims can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 1-29 remain pending, and claims 1-9, 12, 17-19, and 22-27 are being examined.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-9, 12, 17-19, and 22-27 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant respectfully disagrees that these claims are indefinite. However, to advance the prosecution of the above-identified application, claims 1, 7-9, and 22-27 have been amended.

Claim 1, and the claims dependent therefrom, have been amended to recite that a therapeutically effective amount of the agent is administered, and that the agent provides pain relief for at least about two months, as the Examiner suggested. Applicant submits that a therapeutically effective amount of the agent providing pain relief for at least about two months is less than an amount used to kill a patient.

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Claim 7 has been amended by replacing "a" with --the--, as suggested by the Examiner. Claim 8 has been amended to define which precursors of substance P are being recited. Claim 9 has been amended to recite that the substance P analogue is a "functional" analogue, as suggested by the Examiner. Claims 22-27 have been amended to recite how the pain is quantified in order to provide a determination of the amount of pain reduction. Although pain may be a subjective experience, pain may be quantified using a scale or ranking, as understood by persons of ordinary skill in the art. By allowing a patient to quantify his or her pain using a scale, the amount of pain relief can be effectively determined.

In view of the above, applicant submits that the claims satisfy the requirements of 35 U.S.C. § 112, second paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejections Under 35 U.S.C. §§ 102 and 103

Claims 1-9 and 19 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by First (U.S. Patent No. 6,063,768). Claims 1-9, 12, 17-19, and 22-27 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over First.

Claim 1 and the claims dependent therefrom have been amended, as set forth above. Applicant respectfully traverses the rejections as they relate to the amended claims.

Applicant submits that First does not disclose, teach, or suggest the present invention. For example, First does not

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disclose, teach, or even suggest administration of an agent comprising a botulinum toxin component conjugated to a substance P component. First discloses the use of botulinum toxin, not a conjugate of a botulinum toxin component and a substance P component, to treat neurogenic inflammation pain. Because First does not disclose each and every element of the amended claims, for example because First does not disclose or teach administration of an agent that comprises a conjugate of a botulinum toxin component and a substance P component, the disclosure of First cannot be used to properly reject the claims under 35 U.S.C. § 102.

In addition, First fails to provide any motivation or incentive for a person of ordinary skill in the art to modify the teachings of First to obtain the present claims. For example, First fails to even suggest administering, and provides no motivation or incentive to one of ordinary skill in the art to administer, any conjugate of botulinum toxin, and a conjugate of a botulinum toxin component and a substance P component for any purpose, let alone to a patient to treat neurogenic inflammation pain, as recited in the present claims. Thus, applicant submits First cannot be used to properly reject the claims under 35 U.S.C. § 103.

In view of the above, applicant submits that the present claims, and claims 1-9, 12, 17-19, and 22-27 in particular, are not anticipated by First under 35 U.S.C. § 102(b), and are unobvious from and patentable over First under 35 U.S.C. § 103(a).

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Obviousness-Type Double Patenting Rejections

Claims 1-9, 12, 17-19, and 22-27 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 2, 4-7, 9, 11-20 of U.S. Patent No. 6,500,436.

Submitted herewith is a Terminal Disclaimer, and required fee, in response to the obviousness-type double patenting rejections. Applicant submits that this rejection has been overcome.

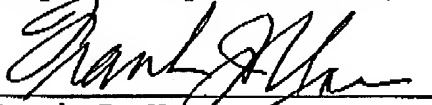
In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

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In conclusion, applicant has shown that the present claims are not subject to rejection for double patenting, satisfy the requirements of 35 U.S.C. § 112, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-9, 12, 17-19, and 22-27 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,

Date: May 28, 2004

  
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